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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/049,695	03/27/1998	PATRICIA A. BILLING-MEDEL	6066.US.PI	5913
23492	7590	01/05/2004		
STEVEN F. WEINSTOCK ABBOTT LABORATORIES 100 ABBOTT PARK ROAD DEPT. 377/AP6A ABBOTT PARK, IL 60064-6008			EXAMINER CANELLA, KAREN A	
			ART UNIT 1642	PAPER NUMBER

DATE MAILED: 01/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/049,695	<b>Applicant(s)</b> BILLING-MEDEL ET AL.	
	<b>Examiner</b> Karen A Canella	<b>Art Unit</b> 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 7-10, 13, 14, 16, 19-27 and 40-45 is/are pending in the application.  
     4a) Of the above claim(s) 7-10, 13, 14, 16 and 19-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 40-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
     a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____                                    |

### DETAILED ACTION

1. Claims 28-39 have been canceled. Claims 40-45 have been added. Claims 7-10, 13, 14, 16, 19-27 and 40-45 are pending. Claims 7-10, 13, 14, 16 and 19-27, drawn to non-elected inventions, remain withdrawn from consideration. Claims 40-45 are under consideration
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.
3. Claim 40 is objected to because of the following informalities: The claim lacks a comma in between SEQ ID NO:24 and SEQ ID NO:25. Appropriate correction is required.
4. Claims 40-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is made for the same reasons of record  

Claims 40 and 43 recite "degenerate coding sequences thereof" after the recitation of SEQ ID NO representing polynucleotide sequences. Without recitation of a polypeptide sequence to which the degenerate coding sequences are directed, the metes and bonds of this limitation cannot be construed. Applicant has amended the claims to recite "degenerate coding sequences of SEQ ID NO:23, 24 and 25" in order to obviate this rejection. However, SEQ ID NO: 23, 24 and 25 are polynucleotide sequences not polypeptide, and therefore do not provide any limitation with regard to the translation frame.
5. Claims 43-45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 43-45 encompass DNA molecules comprising polynucleotides consisting of SEQ ID NO:23, 24 or 25, and as such read on DNA molecules comprising SEQ ID NO:23, 24 and 25 because said polynucleotides can be comprised within the larger DNA molecule.

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The specification teaches that SEQ ID NO:23, 24 and 25 are EST sequences, and thus represent partial cDNAs. The specification discloses that SEQ ID NO:5 is the consensus sequence deduced from the individual partial sequences. On page 52, lines 18-26 the specification states that the first forward frame of SEQ ID NO:5 was found to be an open reading frame encoding SEQ ID NO:16. The specification does not disclose whether or not a given EST sequence crosses an intron/exon junction, therefore polynucleotides which comprise the EST sequences can be genomic sequences having introns and regulatory regions which have not been described, in addition to cDNA sequences which have not been described. Each of SEQ ID NO: 23, 24 and 25 represent a separate genus of polynucleotides which minimally comprises the EST sequences. Further, claims 43-45 encompass "degenerate coding sequences thereof" without a limitation regarding a polypeptide which is being encoded. When given the broadest reasonable interpretation, the coding sequences can be appraised from any frame, both forward and backward, of the given EST sequences. It is reasonable to conclude that proteins translated from polynucleotides which start at different frames within said polynucleotides would result in a completely different amino acid sequence. The degenerate coding sequences thereof for each EST sequence thus comprise an additional set of polynucleotide genres which encompass polynucleotides which are not related by function to the instant SEQ ID NO:5 which has been predicted to encode SEQ ID NO:16. A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs defined by the nucleotide sequence falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed Cir 1997). Here the specification discloses only a single common structural feature shared by members of the claimed genres, i.e. SEQ ID NO: 1, 2, 23, 24 and 25, and the genres are highly variant because they encompass polynucleotides which differ in functional attributes from the claimed EST sequences. Because the genres are highly variant the disclosure of the partial sequences of SEQ ID NO:1, 2, 23, 24 and 25 fail to describe the claimed genres. One of skill in the art would conclude that applicant was not in possession of the claimed genres for each of SEQ ID NO: 23, 24 and 25.

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6. Claims 43-45 are rejected under 35 U.S.C. 102(e) as being anticipated by Lal et al (US 5,856,139. Claim 43 is drawn to a DNA molecule comprising a polynucleotide consisting of SEQ ID NO:23, 24 or 25. Claim 44 embodies the DNA molecule of claim 43 wherein said polynucleotide is produced by recombinant techniques. Claim 45 embodies the DNA molecule of claim 43 wherein said polynucleotide is produced by synthetic techniques.

Lal et al disclose the polynucleotide of Sequence 2 which comprises SEQ ID NO:24 and 25 as evidenced by the attached alignments provided in the previous Office action. Lal et al disclose obtaining said polynucleotides by synthetic and recombinant techniques (column 8, lines 36-44, column 10, lines 30-38 and column 11, lines 32-41).

7. All other rejections and objections as set forth in the previous Office action are withdrawn..

### ***Conclusion***


Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703)

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308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
Karen A. Canella, Ph.D.

Primary Examiner, Group 1642

January 1, 2004